

United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/509,910	04/03/2000	WALTER SEBALD	LEA32545	6688
7590 12/01/2003		EXAMINER		
JEFFREY M GREENMAN BAYER CORPORATION			SEHARASEYON, JEGATHEESAN	
400 MORGAN LANE			ART UNIT	PAPER NUMBER
WEST HAVEN	N, CT 06516		1647	

DATE MAILED: 12/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

4						
		Application No.	Applicant(s)			
		09/509,910	SEBALD, WALTER			
	Office Action Summary	Examiner	Art Unit			
		Jegatheesan Seharaseyon	1647			
Period fo	The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply					
THE - Exte after - If the - If NO - Failt - Any	IORTENED STATUTORY PERIOD FOR REPLY MAILING DATE OF THIS COMMUNICATION. ensions of time may be available under the provisions of 37 CFR 1.13 rs IX (6) MONTHS from the mailing date of this communication. The period for reply specified above is less than thirty (30) days, a reply of period for reply is specified above, the maximum statutory period we are to reply within the set or extended period for reply will, by statute, reply received by the Office later than three months after the mailing ed patent term adjustment. See 37 CFR 1.704(b).	36(a). In no event, however, may a reply be timed within the statutory minimum of thirty (30) days will apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	nely filed s will be considered timely. the mailing date of this communication. D (35 U.S.C. § 133)			
	Responsive to communication(s) filed on 02 Se	entember 2003				
		action is non-final.				
	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.						
Disposit	ion of Claims					
	☑ Claim(s) <u>9 and 10</u> is/are pending in the application.					
	4a) Of the above claim(s) is/are withdrawn from consideration.					
	Claim(s) is/are allowed.					
	☑ Claim(s) 9 and 10 is/are rejected.					
	Claim(s) is/are objected to.	alastian rasuiran ant				
8) Claim(s) are subject to restriction and/or election requirement.						
	ion Papers					
	9) The specification is objected to by the Examiner.					
10)[10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.					
	Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).					
11)	Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).					
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. §§ 119 and 120						
	12)⊠ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).					
a)[a) ⊠ All b) ☐ Some * c) ☐ None of:					
	1. Certified copies of the priority documents	have been received.				
	 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage 					
	application from the International Bureau (PCT Rule 17.2(a)).					
* S	* See the attached detailed Office action for a list of the certified copies not received.					
13)[_] A	13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet.					
3	37 CFR 1.78.					
	a) The translation of the foreign language provisional application has been received.					
14)∐ A	14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific					
reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.						
Attachment	i(s)					
	e of References Cited (PTO-892)	4) 🔲 Interview Summary (PTO-413) Paper No(s)			
	e of Draftsperson's Patent Drawing Review (PTO-948)	5) Notice of Informal Pa	tent Application (PTO-152)			
יי ני Iniom	nation Disclosure Statement(s) (PTO-1449) Paper No(s)	6) Other: .				

Art Unit: 1647

DETAILED ACTION

1. This Office action is response to the reply and remarks filed on 9/02/2003.

- 2. The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.
- 3. Any objection or rejection of record, which is not expressly repeated in this action, has been overcome by Applicant's response and withdrawn.

Claim Rejections - 35 USC § 102, maintained

4. The rejection of claims 9 and 10 under 35 U.S.C. 102(e) as being anticipated by Greve et al. (U.S. Patent No: 6,028,176) is maintained. Applicants' arguments have been fully considered but are not found to be persuasive. Applicant asserts that in order to anticipate under 35 U.S.C 102 each and every element of a claimed invention must be disclosed within a single prior art. The Office agrees with the assertion. It is argued by the Applicant that Greve et al. does not teach or disclose IL-4 muteins comprising amino acid substitutions at position, 7, 123 and 125. In addition, it is also argued that the reference dose not teach or disclose IL-4 muteins with a reduced affinity and/or an altered specificity to the γ subunit of the IL-4 receptor. However, contrary to Applicants arguments, the Office action of 3/11/2003 clearly indicated that Greve et al. teaches the production of the IL-4 muteins L11A, K12A, N15 A and N15D (see Table 1). In addition, changes in affinity are discussed in columns 16 and 17. Furthermore, the reference also teaches the altered specificity due to amino acid changes (column 18, line32-45). Furthermore, it also discusses multiple amino acid changes with additional changes at positions 121 and 124 and its effect on the binding and specificity (see column 15-18).

Therefore, the disclosure of Greve et al. teaches every limitation of both claims 9 and 10.

5. New Claim rejections necessitated by the amendment.

Claim Rejections - 35 USC § 112

- 6. Claims 9 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- 6a. Claims 9 and 10 are rejected as indefinite due the amendment to the claims. If protein of claim 9 can have the substitutions of claim 10, what else could it have? Is there any structure required?
- 6. No claims are allowable over prior art.
- 7. **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

Art Unit: 1647

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

CONTACT INFORMATION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon whose telephone number is 703-305-1112. The examiner can normally be reached on M-F: 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 703-308-4623. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

LORRAINE SPECTOR PRIMARY EXAMINER

JS